REMARKS

Reconsideration of the rejections set forth in the Office Action dated June 13, 2007 is respectfully requested in view of the foregoing amendments and following remarks. Applicants petition for a 1-month extension of time in which to file this response. A separate Petition is enclosed. Following amendments, claims 1-5, and 14 will be pending in the application.

I. Amendments

Claim 1 has been amended to delete the language "an autoimmune condition or a viral infection" and add the language "multiple sclerosis." Support for the amendment can be found throughout the specification, including, e.g., at ¶¶ [0060] – [0073].

Claim 1 has further been amended to recite, "wherein the interferon-tau has at least 90% sequence homology to the polypeptide of SEQ ID NO: 2." Support for the amendment can be found, e.g., at ¶¶ [0039].

Claim 5 has been amended to conform to amended claim 1.

Claims 6-13 and 15 have been canceled, without prejudice or disclaimer.

No new matter has been added.

II. Rejections under 35 U.S.C. § 112, first paragraph (enablement)

Claims 1, 2, 4-6, 14, and 15 were rejected under 35 U.S.C. § 112, first paragraph, as allegedly not enabled by the specification. Specifically, the Examiner asserts that the breath of the claims is excessive because (A) the claims read on "any protein with 70% or greater homology to known IFN-τ sequences" (Office Action at 3) and (B) the claims are allegedly not enabled for an autoimmune disorder other than multiple sclerosis (Office Action at 4).

The rejections are traversed in view of the following arguments and foregoing amendment.

Standard

The standard for establishing whether an application's disclosure satisfies the enablement requirement is whether one skilled in the art could practice the claimed

invention without undue experimentation. An application need not teach and preferably omits that which is known in the art. M.P.E.P. at 2164.01.

Analysis

With respect to (A), Applicants first point out that the rejected claims required the polypeptide to be "interferon tau." Interferon tau is a recognized subset of interferon polypeptides. Therefore, the Examiner's assertion that the claims encompassed *any* polypeptide with 70% or greater homology to known interferon sequences (Office Action at 3) was incorrect. The claims explicitly require that the polypeptide be an interferon tau.

To illustrate what was known in the art about interferon tau, Applicants provide three references (Exhibits A-C), attached hereto. Roberts, et al. ((1998) *J. Interferon Cytokine Res.* 18:805-16; Exhibit A) includes Table 3 which describes several interferon tau genes from ruminants and discusses reasons to suspect that human interferon tau genes may not exist. Radhakrishnan, et al. ((1999) *J. Mol. Bio.* 286:151-62; Exhibit B) describes the crystal structure of ovine interferon-tau and structural features and amino acids believed to be important for receptor binding and biological activity. WO 94/10313 (Exhibit C) describes the production of interferon-tau polypeptides and their derivatives as well as structure/function relationships. These exhibits make clear that interferon-tau is known in the art and much is known about structure-function relationships.

In view of what is know in the art about interferon-tau and the level guidance in the specification, Applicants submit that the specification provides more than adequate guidance for practicing the full scope of the pending claims.

Nonetheless, to advance prosecution, Applicants have amended claim 1 (from which all other pending claims depend) to recite "wherein the interferon-tau has at least 90% sequence homology to the polypeptide of SEQ ID NO: 2." In addition to requiring that the polypeptide is an interferon tau, the claims as amended require 90% homology to a particular interferon tau (i.e., SEQ ID NO: 2). Applicants submit that one skilled in the art can readily practice the full scope of the claimed invention without undue experiment given the amended claim language in view of what is known in the art about interfereon-tau.

Accordingly, withdrawal of the rejection is respectfully requested.

With respect to (B), Applicants have amended claim 1 (from which all other pending claims depend) to recite multiple sclerosis. Dependent claims not directed to multiple sclerosis are canceled without prejudice or disclaimer. These amendments presumably obviate the rejection.

Applicants believe the remarks and amendments addresses the rejections. Withdrawal of the enablement rejections is respectfully requested.

III. Rejection under 35 U.S.C. § 112, first paragraph (written description)

Claims 1, 2, 4-6, 14, and 15 were rejected under 35 U.S.C. § 112, first paragraph, as allegedly lacking written description for interferon-tau polypeptides.

Standard

The standard for establishing whether an application's disclosure satisfies the written description is whether one skilled in the art can reasonably conclude that Applicant had possession of the claimed invention. What is conventional or well known to one of ordinary skill in the art need not be disclosed in detail. M.P.E.P. at 2163.

Analysis

As noted above with the respect to the enablement rejection, the rejected claim required the polypeptide to be "interferon tau." Interferon tau is a recognized subset of interferon polypeptides. Therefore, the Examiner's assertion that the claims read on *any* polypeptide with 70% or greater homology to known interferon sequences (Office Action at 5) was incorrect. As illustrated by Exhibits A-C, interferon-tau is known in the art and structure-function studies have been performed. As noted above, what is conventional or well known to one of ordinary skill in the art need not be disclosed in detail.

To advance prosecution, Applicants have amended claim 1 (from which all other pending claims depend) to recite "wherein the interferon-tau has at least 90% sequence homology to the polypeptide of SEQ ID NO: 2." In addition to requiring that the polypeptide is an interferon tau, the claims as amended require 90% homology to a

particular interferon tau (i.e., SEQ ID NO: 2). Applicants submit that this claim language is more than adequately supported by the specification in combination with what is known in the art.

Accordingly, withdrawal of the rejection is respectfully requested.

III. Rejection under 35 U.S.C. § 103

Claims 1, 2, 4-6, 14, and 15 were rejected under 35 U.S.C. § 103(b) as allegedly obvious over of Soos et al. (WO 97/33607) in view of van Boxel-Dezaire et al. ((1999) *Ann. Neurol.* 45:695-703).

The rejection is traversed.

A. The Pending Claims

Independent claim 1, as amended, recites, "[a] method of increasing IL-10/IFNγ ratio in subjects suffering from multiple sclerosis, comprising orally administering interferon-tau to the subject at a daily dosage of greater than about 5×10^8 Units to produce an initial measurable increase in the subject's blood IL-10 level, relative to the blood IL-10 level in the subject in the absence of interferon-tau administration, with (i) no substantial change in the subject's blood IFNγ level relative to the IFNγ level in the absence of interferon-tau administration or (ii) a decrease in the subject's blood IFNγ level relative to the IFNγ level in the absence of interferon-tau administration, and continuing to orally administer interferon-tau to the subject on a regular basis of at least several times per week, independent of changes in the subject's blood IL-10 level, until a desired clinical endpoint is achieved, wherein the interferon-tau has at least 90% sequence homology to the polypeptide of SEQ ID NO: 2.

B. The Cited References

Soos et al. (WO 97/33607) teach orally administering a therapeutically-effective amount of interferon-tau at a dosage of up to 1×10^8 Units/day, and preferably at a dosage of from 1×10^6 to 1×10^7 Units/day (page 5, lines 11-13; page 20, lines 2-4).

van Boxel-Dezaire et al. describe the relationship between multiple sclerosis and IL-10 mRNA levels. The reference does not address interferon-tau.

C. Analysis

Among the considerations in determining whether a claim is obvious in view of a combination of cited references is whether the references teach each and every element of the claimed invention.

In the present case, none of the references, separately or in combination, teach orally administering interferon-tau to a subject at a daily dosage of greater than about 5 x 10^8 Units, as required by claim 1. While Soos et al. teach that, in view of its lower toxicity, interferon-tau can be administered at higher doses than, e.g., interferon-beta (page 20, lines 2-5), this teaching is *already reflected* in the high dosages described in the reference (i.e., up to 1 x 10^8 Units/day). This teaching of lower toxicity is not an invitation to administer yet higher doses than already described. Since van Boxel-Dezaire et al. do not discuss interferon-tau, the reference does not cure the defect with respect Soos et al.

Thus, since none of the references, separately or in combination, teach administering interferon-tau at a dosage of greater than about 5 x 10^8 Units/day, Applicants submit that the present claims are nonobvious. Withdrawal of the rejection is respectfully requested.

V. Double-Patenting Rejections

Claim 1-6, 14, and 15 were rejected under the judicially-created doctrine of obviousness-type double patenting as being unpatentable over claims in related applications, as shown in the following Table:

Application No.	Claims
10/825,068	1, 3, 6, 8, 10, 11
10/825,457	1-6
11/040,706	1-6, 25
10/884,741	1-4, 8-10, 19-22
11/112,369	1, 17, 18

The Examiner noted that a timely filed Terminal Disclaimer in compliance with 36 C.F.R. §1.321(c) would overcome an actual or provisional rejection on this ground. Enclosed herewith is an executed Terminal Disclaimer filed in accordance with C.F.R. §1.321(b) and (c) which disclaims the terminal portion of any patent issuing on the

instant application that extends beyond the expiration of the Applications listed in the above Table.

Applicants submit that the filing of a Terminal Disclaimer overcomes the rejection for obviousness-type double patenting. Withdrawal of the rejection is respectfully requested.

V. Conclusion

Applicants believe that the present application is fully in condition for allowance. Early notice to this effect is earnestly requested. If the Examiner has any questions or believes a telephone conference would expedite prosecution of this application, the Examiner is encouraged to call the undersigned at (650) 838-4300.

Respectfully submitted,
Perkins Coie LLP

Date: Oct. 12, 2007

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